



1636
#

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Havenga et al.

Serial No.: 09/665,472

Filed: September 20, 2000

For: GENE DELIVERY VECTORS
PROVIDED WITH A TISSUE TROPISM
FOR DENDRITIC CELLS

Confirmation No.: 8505

Examiner: G. G. Leffers, Jr.

Group Art Unit: 1636

Attorney Docket No.: 2578-4489US

#10

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

April 3, 2003
Date

Signature

Jayna M. Lofgran
Name (Type/Print)

RECEIVED

APR 14 2003
TECH CENTER 1600/2900

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08A be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as

defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US- 4,487,829 #	12/11/1984	Sharp et al.
US- 4,517,686 #	05/21/1985	Ruoslahti et al.
US- 4,578,079 #	03/25/1986	Ruoslahti et al.
US- 4,589,881 #	05/20/1986	Pierschbacher et al.
US- 4,593,002 #	06/03/1986	Dulbecco
US- 4,792,525 #	12/20/1988	Ruoslahti et al.
US- 4,797,368 #	01/10/1989	Carter et al.
US- 4,956,281 #	09/11/1990	Wallner et al.
US- 5,024,939 #	06/18/1991	Gorman
US- 5,096,815 #	03/17/1992	Ladner et al.
US- 5,166,320 #	11/24/1992	Wu et al.
US- 5,198,346 #	03/30/1993	Ladner et al.
US- 5,204,445 #	04/20/1993	Plow et al.
US- 5,223,394 #	06/29/1993	Wallner
US- 5,223,409 #	06/29/1993	Ladner et al.
US- 5,240,846 #	08/31/1993	Collins et al.
US- 5,246,921 #	09/21/1993	Reddy et al.
US- 5,332,567 #	07/26/1994	Goldenberg
US- 5,349,053 #	09/20/1994	Landolfi
US- 5,403,484 #	04/04/1995	Ladner et al.
US- 5,436,146 #	07/25/1995	Shenk et al.
US- 5,443,953 #	08/22/1995	Hansen et al.
US- 5,474,935 #	12/12/1995	Chatterjee et al.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US- 5,521,291 #	05/28/1996	Curiel et al.
US- 5,534,423 #	07/09/1996	Palsson et al.
US- 5,543,328 #	08/06/1996	McClelland et al.
US- 5,547,932 #	08/20/1996	Curiel et al.
US- 5,552,311 #	09/03/1996	Sorscher et al.
US- 5,559,099 #	09/24/1996	Wickham et al.
US- 5,571,698 #	11/05/1996	Ladner et al.
US- 5,622,699 #	04/22/1997	Ruoslahti et al.
US- 5,712,136 #	01/27/1998	Wickham et al.
US- 5,731,190 #	03/24/1998	Wickham et al.
US- 5,756,086 #	05/26/1998	McClelland et al.
US- 5,770,442 #	06/23/1998	Wickham et al.
US- 5,922,315 #	07/13/1999	Roy
US- 6,127,525 #	10/03/2000	Crystal et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
259212 #	03/09/1988	EP
2078631 #	03/19/1990	JP
WO 91/00360 #	01/10/1991	PCT
WO 91/05805 #	05/02/1991	PCT
WO 91/05871 #	05/02/1991	PCT
WO 92/02553 #	02/20/1992	PCT
WO 92/13081 #	08/06/1992	PCT
WO 93/03769 #	03/04/1993	PCT
WO 93/06223 #	04/01/1993	PCT
WO 93/07282 #	04/15/1993	PCT

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 93/07283 #	04/15/1993	PCT
WO 94/08026 #	04/14/1994	PCT
WO 94/10323 #	05/11/1994	PCT
WO 94/11506 #	05/26/1994	PCT
WO 94/15644 #	07/21/1994	PCT
WO 94/17832 #	08/14/1994	PCT
WO 94/24299 #	10/27/1994	PCT
WO 94/26915 #	11/24/1994	PCT
WO 95/05201 #	02/23/1995	PCT
WO 95/06745 #	03/09/1995	PCT
WO 95/14785 #	06/01/1995	PCT
WO 95/16037 #	06/15/1995	PCT
WO 95/21259 #	08/10/1995	PCT
WO 95/26412 #	10/05/1995	PCT
WO 95/27071 #	10/12/1995	PCT
WO 95/31187 #	11/23/1995	PCT
WO 95/31566 #	11/23/1995	PCT
WO 96/00790 #	01/11/1996	PCT
WO 96/07739 #	03/14/1996	PCT
WO 96/10087 #	04/04/1996	PCT
WO 96/13597 #	05/09/1996	PCT
WO 96/14837 #	05/23/1996	PCT
WO 96/17073 #	06/06/1996	PCT
WO 96/18740 #	06/20/1996	PCT
WO 96/26281 #	08/29/1996	Wickham et al.
WO 97/00326 #	01/03/1997	PCT
WO 97/24453 #	07/10/1997	PCT

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 97/38723 #	10/23/1997	PCT
WO 98/07865 #	02/26/1998	PCT
WO 98/11221 #	03/19/1998	PCT
WO 98/13499 #	04/02/1998	PCT
WO 98/22609 #	05/28/1998	PCT
WO 98/32842 #	07/30/1998	PCT
WO 98/40509 #	09/17/1998	PCT

Other Documents

DE JONG et al., "Adenoviruses from Human Immunodeficiency Virus-Infected Individuals, Including Two Strains That Represent New Candidate Serotypes Ad50 and Ad51 of Species B1 and D, Respectively," 37(12) Journal of Clinical Microbiology 3940-45, American Society for Microbiology (Dec. 1999). #

ALBIGES-RIZO et al., "Human Adenovirus Serotype 3 Fiber Protein," Journal of Biological Chemistry, 266(6), 3961-3967 (1991). #

BAI et al., "Mutations That Alter an Arg-Gly-Asp (RGD) Sequence in the Adenovirus Type 2 Penton Base Protein Abolish Its Cell-Rounding Activity and Delay Virus Reproduction in Flat Cells," Journal of Virology, 67(9), 5198-5205 (1993). #

BAILEY et al., "Phylogenetic Relationships among Adenovirus Serotypes," Virology, 205, 439-452 (1994). #

BALL-GOODRICH et al., "Parvoviral Target Cell Specificity: Acquisition of Fibrotropism by a Mutant of the Lymphtropic Strain of Minute Virus of Mice Involves Multiple Amino Acid Substitutions within the Capsid," Virology, 184, 175-186 (1991). #

BATRA et al., "Receptor-mediated gene delivery employing lectin-binding specificity," Gene Therapy, 1, 255-260 (1994). #

BOURSNELL et al., "In vitro construction of a recombinant adenovirus Ad2:Ad5," Gene, 13, 311-317 (1981). #

Other Documents

CAILLET-BOUDIN et al., "Functional and Structural Effects of an Ala to Val Mutation in the Adenovirus Serotype 2 Fibre," J. Mol. Biol., 217, 477-486 (1991). #

CHROBOCZEK et al., "The Sequence of the Genome of Adenovirus Type 5 and Its Comparison with the Genome of Adenovirus Type 2," Virology, 186, 280-285 (1992). #

CHU et al., "Cell targeting with retroviral vector particles containing antibody-envelope fusion proteins," Gene Therapy, 1, 292-299 (1994). #

COTTEN et al., "High-efficiency receptor-mediated delivery of small and large (48 kilobase gene constructs using the endosome-disruption activity of defective or chemically inactivated adenovirus particles," Proc. Natl. Acad. Sci. USA, 89, 6094-6098 (1992). #

COTTEN et al., "Transferrin-polycation-mediated introduction of DNA into human leukemic cells: Stimulation by agents that affect the survival of transfected DNA or modulate transferrin receptor levels," Proc. Natl. Acad. Sci. USA, 87, 4033-4037 (1990). #

CRAWFORD-MIKSZA et al., "Adenovirus Serotype Evolution Is Driven by Illegitimate Recombination in the Hypervariable Regions of the Hexon Protein," Virology, 224, 357-367 (1996). #

CRAWFORD-MIKSZA et al., "Analysis of 15 Adenovirus Hexon Proteins Reveals the Location and Structure of Seven Hypervariable Regions Containing Serotype-Specific Residues," J. Virol., 70(3), 1836-1844 (1996). #

CROMPTON et al., "Expression of a foreign epitope on the surface of the adenovirus hexon," J. Gen. Virol., 75(1), 133-139 (1994). #

CRYSTAL, Ronald G., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," Science, 270, 404-410 (1995). #

CURIEL et al., "Adenovirus enhancement of transferrin-polylysine-mediated gene delivery," Proc. Natl. Acad. Sci. USA, 88, 8850-8854 (1991). #

CURIEL et al., "High-Efficiency Gene Transfer Mediated by Adenovirus Coupled to DNA-Polylysine Complexes," Human Gene Therapy, 3, 147-154 (1992). #

Other Documents

- DEFER et al., "Human Adenovirus-Host Cell Interactions: Comparative Study with Members of Subgroups B and C," *Journal of Virology*, 64(8), 3661-3673 (1990). #
- DUPUIT et al., "Regenerating Cells in Human Airway Surface Epithelium Represent Preferential Targets for Recombinant Adenovirus," *Human Gene Therapy*, 6, 1185-1193 (1995). #
- ETIENNE-JULAN et al., "The efficiency of cell targeting by recombinant retroviruses depends on the nature of the receptor and the composition of the artificial cell-virus linker," *Journal of General Virology*, 73, 3251-3255 (1992). #
- FALGOUT et al., "Characterization of Adenovirus Particles Made by Deletion Mutants Lacking the Fiber Gene," *Journal of Virology*, 62(2), 622-625 (1988). #
- GALL et al., "Adenovirus type 5 and 7 capsid chimera: Fiber replacement alters receptor tropism without affecting primary immune neutralization epitopes," 70(4) *Journal of Virology* 2116-23 (1996). #
- GALL et al., "Construction and characterization of Hexon-Chimeric Adenoviruses: Specification of adenovirus serotype," 72(12) *Journal of Virology* 10260-64 (1998). #
- GREBER et al., "Stepwise Dismantling of Adenovirus 2 during Entry into Cells," *Cell*, 75, 477-486 (1993). #
- GREEN et al., "Evidence for a repeating cross- β sheet structure in the adenovirus fibre," *EMBO Journal*, 2(8), 1357-1365 (1983). #
- HAN et al., "Ligand-directed retroviral targeting of human breast cancer cells," *Proc. Natl. Acad. Sci. USA*, 92, 9747-9751 (1995). #
- HENRY et al., "Characterization of the Knob Domain of the Adenovirus Type 5 Fiber Protein Expressed in *Escherichia coli*," *Journal of Virology*, 68(8), 5239-5246 (1994). #
- HONG et al., "The Amino Terminus of the Adenovirus Fiber Protein Encodes the Nuclear Localization Signal," *Virology*, 185(2), 758-767 (1991). #
- HORVATH et al., "Nonpermissivity of Human Peripheral Blood Lymphocytes to Adenovirus Type 2 Infection," *Journal of Virology*, 62(1), 341-345 (1988). #

Other Documents

- HUANG et al., "Upregulation of Integrins $\alpha v\beta 3$ and $\alpha v\beta 5$ on Human Monocytes and T Lymphocytes Facilitates Adenovirus-Mediated Gene Delivery," *Journal of Virology*, 69(4), 2257-2263 (1995). #
- KARAYAN et al., "Oligomerization of Recombinant Penton Base of Adenovirus Type 2 and Its Assembly with Fiber in Baculovirus-Infected Cells," *Virology*, 202, 782-795 (1994). #
- KASS-EISLER et al., "Quantitative determination of adenovirus-mediated gene delivery to rat cardiac myocytes *in vitro* and *in vivo*," *Proc. Natl. Acad. Sci. USA*, 90, 11498-11502 (1993). #
- KOMORIYA et al., "The Minimal Essential Sequence for a Major Cell Type-specific Adhesion Site (CS1) within the Alternatively Spliced Type III Connecting Segment Domain of Fibronectin Is Leucine-Aspartic Acid-Valine," *Journal of Biological Chemistry*, 266(23), 15075-15079 (1991). #
- MARAVEYAS et al., "Targeted Immunotherapy - An update with special emphasis on ovarian cancer," *Acta Oncologica*, 32(7/8), 741-746 (1993). #
- MASTRANGELI et al., "*In Vivo* Gene Transfer to the Lung of Experimental Animals Using a Chimeric Ad5/Ad7 Adenovirus Vector," *Ped. Pulm., Suppl.*, 12, 230, Abst. No. 180 (1995). #
- MASTRANGELI et al., "'Sero-Switch' Adenovirus-Mediated *In Vivo* Gene Transfer: Circumvention of Anti-Adenovirus Humoral Immune Defenses Against Repeat Adenovirus Vector Administration by Changing the Adenovirus Serotype," *Human Gene Therapy*, 7, 79-87 (1996). #
- MATHIAS et al., "Multiple Adenovirus Serotypes Use αv Integrins for Infection," *Journal of Virology*, 68(10), 6811-6814 (1994). #
- MAUTNER et al., "Recombination in Adenovirus: DNA Sequence Analysis of Crossover Sites in Intertypic Recombinants," *Virology*, 131, 1-10 (1983). #
- MICHAEL et al., "Addition of a short peptide ligand to the adenovirus fiber protein," *Gene Therapy*, 2, 660-668 (1995). #
- MICHAEL et al., "Binding-incompetent Adenovirus Facilitates Molecular Conjugate-mediated Gene Transfer by the Receptor-mediated Endocytosis Pathway," *Journal of Biological Chemistry*, 268(10), 6866-6869 (1993). #

Other Documents

- MILLER et al., "Targeted vectors for gene therapy," FASEB Journal, 9, 190-199 (1995). #
- NEDA et al., "Chemical Modification of an Ecotropic Murine Leukemia Virus Results in Redirection of Its Target Cell Specificity," Journal of Biological Chemistry, 266(22), 14143-14146 (1991). #
- NEMEROW et al., "Adenovirus entry into host cells: a role for α_v integrins," Trends In Cell Biology, 4, 52-55 (1994). #
- NEMEROW et al., "The Role of α_v Integrins in Adenovirus Infection," Biology of Vitronectins and their Receptors, 177-184 (1993). #
- NOVELLI et al., "Deletion Analysis of Functional Domains in Baculovirus-Expressed Adenovirus Type 2 Fiber," Virology, 185, 365-376 (1991). #
- ORKIN et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy," (1995), file:///F:/NIHrec.htm 1/4/01 1:37 pm. #
- PETERANDERL et al., "Trimerization of the Heat Shock Transcription Factor by a Triple-Stranded α -Helical Coiled-Coil," Biochemistry, 31, 12272-12276 (1992). #
- PRING-ÅKERBLOM et al., "Sequence Characterization and Comparison of Human Adenovirus Subgenus B and E Hexons," Virology, 212, 232-36 (1995). #
- ROBERTS et al., "Three-Dimensional Structure of the Adenovirus Major Coat Protein Hexon," Science, 232, 1148-51 (1986). #
- RUSSELL et al., "Retroviral vectors displaying functional antibody fragments," Nucleic Acids Research, 21(5), 1081-1085 (1993). #
- SIGNÄS et al., "Adenovirus 3 Fiber Polypeptide Gene: Implications for the Structure of the Fiber Protein," Journal of Virology, 53(2), 672-678 (1985). #
- SILVER et al., "Interaction of Human Adenovirus Serotype 2 with Human Lymphoid Cells," Virology, 165, 377-387 (1988). #
- STEVENSON et al., "Selective targeting of human cells by a chimeric adenovirus vector containing a modified fiber protein," 71(6) Journal of Virology, 4782-90 (1997). #

Other Documents

STEWART et al., "Difference imaging of adenovirus: bridging the resolution gap between X-ray crystallography and electron microscopy," EMBO Journal, 12(7), 2589-2599 (1993). #

VERMA et al., "Gene Therapy – promises, problems and prospects," Nature, 389, 239-42 (1997). #

WADELL, G., "Molecular Epidemiology of Human Adenoviruses," Curr. Top. Microbiol. Immunol., 110, 191-220 (1984). #

WAGNER et al., "Coupling of adenovirus to transferrin-polylysine/DNA complexes greatly enhances receptor-mediated gene delivery and expression of transfected genes," Proc. Natl. Acad. Sci. USA, 89, 6099-6103 (1992). #

WATSON et al., "An Antigenic Analysis of the Adenovirus Type 2 Fibre Polypeptide," Journal of Virology, 69, 525-535 (1988). #

WICKHAM et al., "Integrins $\alpha_v\beta_3$ and $\alpha_v\beta_5$ Promote Adenovirus Internalization but Not Virus Attachment," Cell, 73, 309-319 (1993). #

WICKHAM et al., "Integrin $\alpha_v\beta_5$ Selectively Promotes Adenovirus Mediated Cell Membrane Permeabilization," Journal of Cell Biology, 127(1), 257-264 (1994). #

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/348,354

Filed: July 7, 1999

For: CHIMAERIC ADENOVIRUSES.

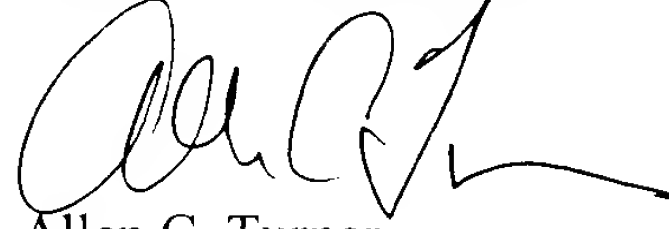
Applicants offer to supply any explanation or discussion of the documents which the Examiner feels is necessary or desirable and which is requested.

This Supplemental Information Disclosure Statement is filed after the mailing date of the first Office Action on the merits.

Serial No. 09/665,472

The fee pursuant to 37 C.F.R. § 1.17(p) is enclosed.

Respectfully submitted,



Allen C. Turner

Registration No. 33,041

Attorney for Applicants

TRASKBRITT

P.O. Box 2550

Salt Lake City, Utah 84110-2550

Telephone: 801-532-1922

Date: April 3, 2003

ACT/jml

Enclosures: Form PTO-1449 or PTO/SB/08

Check No. 4091 in the amount of \$180.00

Document in ProLaw